

### **REMARKS**

The Examiner rejected claims 1-4, 17-23, and 25-30, while withdrawing claims 5-16, 24, and 31-46 from consideration. Claims 1-2, 4, and 30 have been canceled herein without prejudice. Thus, claims 3, 5-16, 17-29, and 31-46 remain pending.

In addition, claim 3 has been amended herein to recite that the nucleic acid segment is operably linked to a promoter, while claims 17, 19-22, and 25-29 have been amended to depend from claim 3. Applicant's specification fully supports these amendments. For example, original claim 30 supports the amendment of claim 3. Thus, no new matter has been added.

In light of these amendments and the following remarks, Applicant respectfully requests reconsideration and allowance of claims 3, 17-23, and 25-29.

#### Oath/Declaration

The Examiner stated that the declaration was defective since it contained a non-initialed or non-dated alteration. Applicant submits herewith a new declaration signed by the inventor. This new declaration does not contain any non-initialed or non-dated alterations. Thus, Applicant respectfully request acknowledgement that the new declaration is in compliance with U.S. Patent and Trademark Office rules.

#### Specification

The Examiner objected to the specification stating that the abstract must be presented on a separate sheet. Applicant respectfully submits herewith the abstract on a separate sheet. The attached Abstract corresponds to the English language Abstract that was published in the PCT application. Therefore, Applicant submits that there is no new matter introduced by these amendments. In light of the above, Applicant respectfully request withdrawal of this objection.

#### Claim Objections

The Examiner objected to claims 17-23 and 25-30 for reading on non-elected embodiments apparently since they depend, directly or indirectly, from one or more non-elected base claims.

Claims 17, 19-23, and 25-30 have been amended to depend from claim 3. Thus, this objection is moot.

Rejections under 35 U.S.C § 112, first paragraph

The Examiner rejected claims 1-4, 17-23, and 25-30 under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. Specifically, the Examiner stated that the “specification does not teach a BNP gene therapy method to inhibit or prevent heart failure in mammal or a BNP gene therapy method to relax cardiac muscle in a mammal.” While acknowledging that Applicant’s specification provides sufficient guidance to make and use a nucleic acid segment that expresses BNP operatively linked to a promoter, the Examiner stated that the claims do not embrace a promoter operatively linked to the nucleic acid segment. In addition, the Examiner stated that the specification does not provide sufficient guidance for a genus of administration routes and that “with respect to using a nucleic acid encoding a chimera of BNP or a BNP from a species different from the mammal in the claimed method, the claimed invention is not considered enabled.”

Applicant respectfully disagrees. Applicant’s specification fully enables the previously claimed invention. To further prosecution, however, claims 1 and 2 have been cancelled herein without prejudice. In addition, independent claim 3 has been amended to recite that the nucleic acid segment is operably linked to a promoter. As the Examiner acknowledged, Applicant’s specification provides sufficient guidance for a person having ordinary skill in the art to make and use the recited nucleic acid segment operatively linked to a promoter.

Applicant’s specification fully enables the presently claimed invention. For example, Applicant’s specification discloses administering nucleic acid molecules encoding BNP locally to cardiac tissue. *See, e.g.*, page 4, lines 12-13 of Applicant’s specification. In fact, Applicant’s specification provides a working example demonstrating the direct injection of an adenoviral vector encoding BNP into cardiac tissue. *See, e.g.*, page 44, lines 27-31 of Applicant’s specification. In addition, Applicant’s specification discloses administering nucleic acid molecules encoding BNP systemically to, for example, to skeletal muscle. *See, e.g.*, page 4, lines 12-13 of Applicant’s specification. In fact, Applicant’s specification describes administering nucleic acid encoding BNP via intramuscular injection into, for example, hind leg

or gluteal muscle tissue. *See, e.g.*, the section extending from page 42, line 21 to page 43, line 19 of Applicant's specification. Applicant's specification also provides a list of multiple published references that describe techniques for administering nucleic acid to various tissues. *See*, pages 52-60 of Applicant's specification. These references are incorporated by reference into Applicant's specification, and copies were previously submitted to the Patent Office. Given the teachings provided throughout Applicant's specification as well as the various nucleic acid delivery techniques known at the time of filing, a person having ordinary skill in the art would have been able to carry out the presently claimed invention without undue experimentation. Thus, Applicant's specification fully enables present claims 3, 17-23, and 25-29.

With respect to the Examiner's comments regarding species-specificity of BNP, it appears that the Examiner cites the Kambayashi *et al.* reference (*Biochem. Biophys. Res. Comm.*, 173:599-605 (1990)) as teaching an absolute requirement of species specificity for BNP to have any biological action. This is not correct. A person having ordinary skill in the art reading the Kambayashi *et al.* reference would have understood that BNP from one species is biologically active in other species. In fact, Table 2 of the Kambayashi *et al.* reference demonstrates that 0.02 nM of human BNP relaxed 50 percent of porcine coronary artery contraction and 12.07 nM of human BNP relaxed 50 percent of rat thoracic aorta contraction. Table 2 also demonstrates that 1.10 nM of rat BNP relaxed 50 percent of porcine coronary artery contraction and 1.11 nM of porcine BNP relaxed 50 percent of rat thoracic aorta contraction. Thus, BNP from one species can possess biological action in a different species.

In light of the above, Applicant respectfully requests the withdrawal of the rejection of claims 3, 17-23, and 25-29 under 35 U.S.C. § 112, first paragraph.

### CONCLUSION

Applicant submits that claims 3, 17-23, and 25-29 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned attorney at the telephone

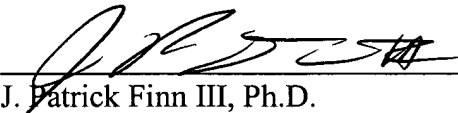
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Serial No. : 09/980,525  
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number below if such will advance prosecution of this application. The Commissioner is authorized to charge any fees or credit any overpayments to Deposit Account No. 06-1050.

Respectfully submitted,

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